

Psychometric properties of the Beliefs about Medicine Questionnaire (BMQ)-AET for Women taking Adjuvant Endocrine Therapies (AET) following early-stage breast cancer

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Abstract:

Objectives: To evaluate the Beliefs about Medicine Questionnaire to explore adherence to adjuvant endocrine therapy after treatment for breast cancer (BMQ-AET). **Method:** Factor structure of the BMQ-AET was explored alongside internal consistency, convergent validity and acceptability. **Results:** The BMQ-AET Specific Scale fitted the original 10 item model. Internal consistency of the BMQ-AET was much improved compared to the original BMQ and convergent validity showed predicted direction of correlation, although correlation with BMQ-AET concerns scale was low. Acceptability was good. **Conclusions:** The evaluation of the BMQ-AET is encouraging, and could facilitate future research around adherence to AET.

Keywords: Beliefs about Medicines Questionnaire (BMQ), BMQ-AET, adherence, Adjuvant Endocrine Therapy (AET), Evaluation, Factor Structure, Convergent validity

Background:

Approximately 80% of breast cancers will be oestrogen receptor positive, and adjuvant endocrine therapy (AET) such as Tamoxifen and Aromatase Inhibitors are recommended (Keen & Davidson, 2003). Adjuvant endocrine therapy taken for five years to ten years has proven effectiveness in preventing recurrence and decreasing mortality from breast cancer (Davies et al., 2013, Gray, 2013, Dowsett et al., 2009, ATAC group, 2008, Howell et al., 2005, Coombes et al., 2004, Goss et al., 2003, Fisher et al., 1996). However, to gain these potential benefits women need to adhere to the medication as prescribed, and reported rates of non-adherence are relatively high. Reviews report that 10-50% of women either do not take the correct dosage at the prescribed frequency or discontinue therapy leading to a 20% increase in mortality (Makubate et al., 2013, McCowan et al., 2008, Banning, 2012, Gotay & Dunn, 2011, Hadji, 2010, Chlebowski & Geller, 2006).

Beliefs about medications as factors influencing patient adherence behaviour have been reported in various clinical groups (van-Dulmen et al., 2007). Investigating women's beliefs about endocrine therapies is crucial to explore their perception of risk and perception of benefit from taking the medication, and develop interventions to improve adherence.

The BMQ has been tested in a wide variety of patient populations and is a valid and reliable measure of medication beliefs (Horne & Weinman, 1999). A recent meta-analytic review reports that across studies, higher adherence was associated with stronger perceptions of necessity of treatment, $OR=1.742$, 95% CI [1.569, 1.934], $p<0.0001$, and fewer Concerns about treatment, $OR=0.504$, 95% CI: [0.450, 0.564], $p<0.0001$. These relationships remained significant when data were stratified by study size, the country in which the research was conducted and the type of adherence measure used (Horne et al., 2013). While it has been used to assess the beliefs and perceptions of women taking endocrine therapy after breast cancer (Cortier et al., 2013, Wouter et al., 2013, Grunfeld et al., 2005), and in other cancers (Llewellyn McGurk Weinman, 2005, Llewellyn McGurk Weinman, 2007), no psychometric evaluation of this measure for this population has been reported.

The BMQ-AET adapted wording of the BMQ Specific Concerns and BMQ Specific

Necessity items to be more relevant to women taking AET following breast cancer. The current study aims to evaluate the factor structure, internal consistency, and acceptability of the BMQ-AET Specific scale in a sample of women prescribed AET for breast cancer.

Methods and Procedures:

Design:

A cross-sectional study was carried out to explore women's experiences of AET. As part of this study, women completed the BMQ-AET within a self-report postal questionnaire.

Sample:

Participants included women aged 36-85 years taking adjuvant endocrine therapy following treatment for breast cancer. These women had previously participated in the Joint Aches Cohort Study (JACS) looking at women's experiences of joint aches, pain and stiffness in breast cancer (Fenlon et al., 2014). During JACS, participants were asked to indicate their willingness to participate in future studies; we re-approached only this subsample for this adherence study. All participants had been diagnosed with primary oestrogen receptive positive breast cancer, and had been prescribed adjuvant endocrine therapy. Exclusion criteria included: women with more advanced cancer, women seriously ill with other conditions, and women who had a poor comprehension of English.

Procedure:

Ethical approval was gained from the University Research Ethics Committee (UREC). Informed consent was gained, and postal questionnaires were sent out in July 2014, with a reminder sent after 3 weeks of non-response. Participants took approximately 20 minutes to complete the questionnaire, which include a range of nominal and multiple choice questions asking about their experiences of taking AET, and two scales: the Medical Adherence Rating Scale (MARS) (Thompson Kulkarni Sergejew, 2000) and the BMQ-AET Specific scales.

Measures:

The Beliefs about Medicines Questionnaire (BMQ) was originally developed to aid understanding of people's perception of medicine regimes, and to help understand adherence to medication. It is an 18 item self-report measure of beliefs about medicine (Horne & Weinman, 1999) derived from a pool of items representing commonly held beliefs about medication in a chronic illness sample (Asthmatic, Cardiac, Diabetic, Renal, Psychiatric, and General)(Horne & Weinman, 1999). Specific (10 items) and General (8 items) beliefs were analysed separately. The measure comprises two sections, each divided into two subscales. The BMQ-Specific comprises two five item subscales: the 'Specific Necessity' subscale (i.e. beliefs about the necessity of taking that specific medication to remain healthy) and the 'Specific Concerns' subscale (i.e. concerns about the negative effects of taking that specific medication). The BMQ-General comprises two 4-item subscales assessing beliefs that medicines are harmful which should not be taken continuously (General-Harm) and that medicines are overused by doctors (General-Overuse). All items of the BMQ are rated on a 5-point likert scale where 1 represents strongly agree, and 5 represents strongly disagree. Scores obtained for the individual items are summed to give a total score for each subscale, and the two sections of the BMQ can be used in combination or separately.

Table 1 identifies the modifications made to the original BMQ for the BMQ-AET. The term 'hormone treatment' is used instead of AET, as the former is a more recognised terminology for this treatment among women. Changes were made in consultation with service users and the expert advisory team for this study that included a breast cancer surgeon, an oncologist, a GP, a health psychologist, a professor of cancer nursing, and a medical sociologist. Most items had minor changes to make the items relevant to the population. However, the item 'my life would be impossible without medicines' was changed to 'taking hormone treatment makes me feel I am taking positive steps to remain well' because AET is not taken by women to reduce side effects of a condition, but to reduce the risk of recurrence of breast cancer and is therefore not relevant to this new population. AET can often cause side effects that make it difficult to continue with the treatment and therefore adherence is more related to taking personal control to avoid the return of a condition rather than controlling a pre-existing condition; this factor was not

covered elsewhere and so deemed a relevant replacement item.

Service users from Independent Cancer Patients' Voice (n=2), cancer experts (n=4), and a representative from the charity Breast Cancer Care evaluated the face validity of the modified items during the development of the questionnaire, with minor adjustment to the final wordings made to ensure comprehension. As items on the General beliefs subscale are not condition specific, it was not necessary to amend wording.

The Medical Adherence Report Scale (MARS-5) (Thompson 2000) assesses adherence to treatment and was used to provide a measure of convergent validity with the BMQ-AET. The MARS-5 consists of five general statements about suboptimal adherence behaviour (I forget to take my AET medicine, I alter the dose of my AET medicine, I stop taking my AET medicine for a while, I decide to skip one of my AET tablets, I take AET less than prescribed) answered on a 5 point scale where 1 represents 'always', and 5 represents 'never'. Items were not summed but used individually in determining types of adherence and non-adherence.

Analysis:

CONsensus-based Standards for the selection of health Measurement INstruments (COSMIN) were used in the selection of evaluation methods for the analysis (Mokkink et al., 2010). Principal Components Analysis (PCA) using direct oblimin rotation was used to explore the factor structure of the modified measure. PCA was chosen over factor analysis because it offers a more pragmatic psychometric solution, reducing the number of observed variables to a smaller number of components (factors) which account for most of the observed variance, thus avoiding some of the potential problems of factor interdependency which are associated with other types of psychometric scale development methods (Bartholomew, 2002). Furthermore, this method mirrors that used in the development and evaluation of the original BMQ (Horne & Weinman, 1999) and it was our intention to be able to compare across these two versions.

The resultant factors were subjected to internal consistency testing using Cronbach's alpha tests. Convergent validity was explored by comparing correlation between the

BMQ-AET and MARS; due to non-parametricity of MARS data, Spearman's correlation tests were used.

Acceptability was examined by exploring missing data, floor/ceiling effects, and face validity was assessed through discussions with service users and clinicians during the development stage of the questionnaire.

Results:

Questionnaires were returned by 211 women (73%), all of whom completed the BMQ-AET scale and 206 completed the MARS. The socio-demographic characteristics and health status of responders are summarised in table 2:

Factor Analysis

Standard diagnostic tests were run to ensure that the data were suitable for factor analysis. Both the Kaiser-Meyer-Olkin test of sampling adequacy ($KMO=.791$) and Bartlett's test of sphericity ($p = <.001$) indicated that the current data were indeed appropriate.

As is usual practice, an initial scree plot analysis was undertaken suggesting a 2 factor solution was the most parsimonious fit for the data, and this corresponded with the factor structure of the original BMQ. More recent practice has also been to consider a Parallel Analysis Monte Carlo simulation (using randomly generated data) to verify the number of required factors (Velicer Eaton Fava, 2000). Using the method described by Hayton et al (2004) (Hayton Allen Scarpello, 2004) which employs an upper bound of the 95% confidence interval for eigenvalues, averaging across 100 random data sets, this procedure confirmed that two resultant factors were appropriate.

Table 3 shows the factor structure matrix (with Kaiser normalisation) resulting from the principle components analysis; this accounted for 56.936 of the total variance (individual factor variances also indicated). Where items loaded onto multiple factors, they were retained only for the factor onto which they loaded most strongly.

Analysis indicated that the factor structure of the BMQ-AET-specific items mapped exactly onto the factor structure of the original scale; the original subscale names were thus retained

whereby Factor 1 became the concerns subscale, and Factor 2 became the necessity scale. Only one item loaded with a very low factor loading ('Hormone treatment is a mystery to me': .283) with the remainder meeting recommended criteria (Stevens Erlbaum, 1992). The low factor loading item was included in the final measure as removing this item did not improve overall psychometric properties of the scale, so it was retained to uphold the original structure of the measure.

Internal consistency

Cronbach's alpha's statistics provide an indication of how well items within a given scale are measuring a similar and stable construct. Typically, subscales with a Cronbach's alpha of less than .7 are considered inadequate, however, Cortina (1993) notes that the method of calculating this statistic is biased by item numbers whereby factors on a scale with fewer items tend usually to produce a lower alpha coefficient as a bi-product of the statistical calculation (Cortina, 1993). As our two subscales of specific beliefs scored alpha coefficients of .776 and .795 for concerns and necessity respectively; even when bearing in mind Cortina's caution (which is relevant given that only 5 items appear in each subscale), these two scales exceed the usual cut-off for acceptability reliability. These figures are aligned with, and in some cases exceed, those reported in the confirmatory factor analysis reported by Horne et al (1999) (Horne & Weinman, 1999).

Convergent Validity

The MARS is a self-report scale of adherence to medication and so provided an adequate measure of convergent validity for these data, whereby we would anticipate a negative correlation between both specific concerns and adherence, and a positive correlation between specific necessity beliefs and adherence. Correlations tests indicated a significant correlation between higher treatment necessity beliefs (BMQ-AET Specific Necessity) and greater adherence (MARS) scores ($r_s = 0.215$, $p = .001$). However, correlations between BMQ-AET Specific Concerns and MARS, while showing the expected direction of association (higher treatment concern beliefs correlated with lower adherence scores), failed to reach statistical significance ($r_s = -0.038$, $p = .100$).

Acceptability

Acceptability of the two individual scales was determined by examining the rate of missing responses to each item, as this provides an indicator of how acceptable the instrument is in a given population (Fitpatrick et al, 1998). The BMQ-AET was completed by all 211 respondents, with only 5 cases having missing responses for one or more items.

Floor and ceiling effects (i.e. the percentage scoring the minimum and maximum score) were examined for the BMQ-AET Specific Concerns and the BMQ-AET Specific Necessity. The Specific Concerns scale had a 3.4% ceiling effect and a 1% floor effect; The Specific Necessity had a 0% ceiling effect and a 8.7% floor effect. As a proportion of up to 15% can be considered a low effect (Terwee et al, 2007), the data shows acceptable ceiling and floor effects.

Discussion

The BMQ-AET was included in a questionnaire survey to explore women's experiences and views of taking AET to identify factors that may be associated with adherence or non-adherence. Independent testing of the BMQ for women prescribed AET following breast cancer has not previously been reported. The BMQ was modified so the wording was suitable to women who were taking AET. The evaluation of the BMQ-AET showed a similar factor structure to the original BMQ Specific subscale (Horne & Weinman, 1999), and we report good internal consistency, encouraging convergent validity and good acceptability within this sample. The modified scale may therefore provide a valuable assessment of women's specific beliefs around AET.

The results show all factors had sufficient factor loading to be included and therefore the original factor structure proposed by Horne (1999) was retained (Horne & Weinman, 1999). This is an important finding as it suggests that the factors represent 'core themes' underpinning common representations of Specific Beliefs in this population which may generalise out to other specific condition groups. One item 'my life would be impossible without medicines' was changed to 'taking hormone treatment makes me feel I am taking positive steps to remain well' because AET is not taken by women to reduce side effects of a condition, but to reduce the risk of recurrence of breast cancer and is therefore not relevant to this new population. AET can often cause side effects that make it difficult to continue with

the treatment and therefore adherence is more related to taking personal control to avoid the return of a condition rather than controlling a pre-existing condition. Although the meaning of the item is slightly different, our psychometric analysis of the scale demonstrates that the new item is still correlated with the other cluster items within the factor group. As such we would suggest that whilst the new item represents some deviation, it is both a pragmatic and psychometrically valid alternation to make the scale relevant to this patient population.

Other studies have reported similar findings in primary care, general medical populations, and mental health populations in the UK and across cultures (Salgado et al, 2013, Cuevas et al, 2011, Browne et al, 2005). In this study, the only exception to this was the item 'Hormone treatment is a mystery to me' and so this may require some further investigation in future uses of the scale. Internal consistency exceeded that reported by Horne in the original evaluation of the measure, which has also been reported in other patient populations, including Stroke and Asthma indicating the generalisability of the BMQ(Sjölander Eriksson Glader, 2013, Horne & Weinman, 2002). Furthermore, results reported good completion rates, acceptable ceiling and floor effects. Face validity of the modified scale was confirmed prior to completion of the questionnaire through consultation with service users and health professionals in the advisory group for this study.

Correlation between BMQ-AET specific subscales and MARS were in the predicted direction, although only the association between treatment necessity beliefs and adherence reached significance. The low correlation between treatment concern beliefs and adherence may have been due to the subjective nature of capturing non-adherence on self-reported measures such as the MARS. Correlation with objective measures, such as pill counts, may provide a better gold standard in future studies. A recent meta-analysis reported significant correlation between both Concerns and Necessity in 33 and 31 studies correlating with MARS(Horne et al, 2013). However, they concluded that stratifying by long term condition and adherence measurement revealed a need for further studies using objective measures in longer term conditions to ensure greater accuracy of measuring non-adherence long-term. Furthermore, a larger study may have given greater power to the study at which point we may expect these effects to more likely reach statistical significance cut-offs. A further meta-analysis exploring associations between the BMQ and different measures of medical adherence concluded that they were correlated at a population level and across the majority of included conditions(Foot et al, 2015).

The current work is based on a self-selected sample that may have presented response bias. The majority of the sample were white Caucasians, so may not be generalizable to ethnic minority groups. While this study reports a correlation between the modified BMQ specific subscales and MARS in the predicted direction, more studies, possibly with larger samples may improve the statistical power to gain significance in both the BMQ-AET Necessity and the BMQ-AET Concerns. Further confirmatory factor analysis is also advised to ensure that this factor structure is retained across multiple samples with less exploratory methods of statistical modelling. Additional studies investigating the psychometric properties of BMQ in other settings and populations may be beneficial to confirm our finding that suggests beliefs provide 'core themes' which are not necessarily population specific.

In conclusion, the BMQ-AET for women prescribed AET following breast cancer has good internal consistency, encouraging convergent validity and good acceptability for the Specific Beliefs about the necessity of and concerns regarding taking AET, and could facilitate future research in this field. Women are prescribed AET for between 5 and 10 years after completion of primary cancer treatment (Gray, 2013, Davies et al., 2013, Goss et al, 2005) and adherence over the entire course is generally low, with consequent increased risk of cancer recurrence and mortality (Makubate et al, 2013, Hersham et al, 2010, McCowan et al., 2008, Partridge et al, 2003). Reasons for not adhering to AET need to be investigated at an individual and population level. The BMQ-AET evaluated in this paper could facilitate a better understanding of factors which affect adherence to AET following breast cancer, to help develop interventions to support patients in engaging with this treatment and coping with the challenging side effects that might result.

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Table 1: Original Specific BMQ (Horne) and Modified Specific BMQ items for women taking AET.

Original BMQ Specific	Modified BMQ Specific (BMQ-AET)
My health at present depends on medicines	My health at present depends on me taking hormone treatment
Having to take this medicine worries me	Having to take hormone treatment worries me
My life would be impossible without medicines	Taking hormone treatment makes me feel I am taking positive steps to remain well
Without my medicines I would be very ill	Without taking hormone treatment I would be more likely to develop breast cancer again
I sometimes worry about the long term effects of taking medicines	I sometimes worry about long term effects of taking hormone treatment
My medicines are a mystery to me	Hormone treatment is a mystery to me
My health in the future is dependent on my medicines	My health in the future will depend on me taking hormone treatment
My medicines disrupt my life	Taking hormone treatment disrupts my life
I sometime worry about becoming too dependent on medicines	I sometimes worry about having hormone treatment over a long period of time
My medicines protect me from becoming worse	Hormone treatment protects me from becoming ill

BMQ=Beliefs about Medicine Questionnaire

Table 2: Demographics and clinical data (n=211)

	Total (N=211)	Non-adherers (N=46)	Adherers (N=165)
Age			
Range	36 to 85 years		
Median	63 years		
36-50 years	31 (15%)	13 (28%)	18 (11%)
51-64 years	80 (38%)	19 (41%)	61 (37%)
≥65 years	87 (41%)	14 (30%)	73 (44%)
Not provided	13 (6%)		
Marital status			
Married	167 (79%)	37 (80%)	130 (79%)
Divorced	21 (10%)	3 (7%)	18 (11%)
Widowed	13 (6%)	2 (4%)	11 (7%)
Single	10 (5%)	4 (9%)	6 (4%)
Employment status:			
Retired	105 (50%)	17 (37%)	88 (53%)
Paid work	87 (41%)	23 (14%)	64 (39%)
Sick leave/unable to work	9 (4%)	3 (7%)	6 (4%)
Unemployed	2 (1%)		2 (1%)
Other	8 (4%)	3 (7%)	5 (3%)
Education			
'O' level	77 (37%)	15 (33%)	62 (38%)
'A' level	33 (16%)	12 (26%)	21 (13%)
College/University	37 (18%)	7 (15%)	30 (18%)
Post-graduate	24 (11%)	7 (15%)	17 (10%)
Other	32 (15%)	5 (11%)	35 (21%)
Not provided	8 (4%)		
Ethnic background:			
White British	207 (98%)	46 (100%)	161 (98%)
Other	3 (2%)		3 (2%)
Diagnosis status			
In breast only	146 (69%)	35 (76%)	111 (67%)
In breast and lymph nodes	65 (31%)	11 (24%)	54 (33%)
AET therapy:			
Tamoxifen	125 (59%)	35 (76%)	90 (55%)
Aromatase Inhibitors	79 (37%)	9 (20%)	70 (42%)
Not sure	7 (3%)	2 (4%)	5 (3%)
Switched type of AET taken	23 (11%)	7 (14%)	15 (9%)
Date started:			
2009	5 (2%)	1 (2%)	4 (2%)
2010	54 (26%)	17 (30%)	37 (22%)
2011	110 (52%)	18 (32%)	92 (56%)
2012	42 (20%)	10 (22%)	32 (19%)

Table 3. Factor structure obtained by principal components analysis of the BMQ-AET specific items (highest factor loading indicated in emboldened text)

	Factor 1	Factor 2
<i>Specific-Concerns</i>		
I sometimes worry about long term effects of taking hormone treatment	.848	-.242
Having to take hormone treatment worries me	.863	-.201
I sometimes worry about having hormone treatment over a long period of time	.890	-.212
Taking hormone treatment disrupts my life	.658	-.023
Hormone treatment is a mystery to me	.283	-.011
<i>Specific-Necessity</i>		
Taking hormone treatment makes me feel I am taking positive steps to remain well	-.484	.541
Without taking hormone treatment I would be more likely to develop breast cancer again	-.157	.734
My health at present depends on me taking hormone treatment	-.001	.784
Hormone treatment protects me from becoming ill	-.161	.781
My health in the future will depend on me taking hormone treatment	-.128	.817
TOTAL VARIANCE EXPLAINED	35.375	21.562

BMQ=Beliefs about Medicine Questionnaire